

### **REMARKS**

Claims 1-8 and 15-18 were pending for purposes of the instant Office Action.

Claims 4 and 15 have been canceled by this amendment. Claim 1 is currently amended as shown above, without prejudice. Support for the amendments can be found, e.g., on pages 44-47 of the specification, describing comparison of test samples to normal controls. Applicants submit that no new matter has been added by virtue of this amendment.

Accordingly, claims 1-3, 5-8 and 16-18 remain pending.

Applicants acknowledge and appreciate the withdrawal of the rejection under 35 U.S.C. 112, second paragraph concerning the recitation of “having” and consisting of” in view of the amendments previously submitted.

### **Indefiniteness Rejections**

Claim 3 remains rejected under 35 U.S.C. 112, second paragraph. Applicants have amended claim 1 (and therefore its dependent claim 3) to provide further clarification as to the greater levels of GPC3 in specific test samples, as compared to normal controls. The test sample, measured in blood, plasma or serum, is compared to a corresponding normal blood, plasma, or serum level of GPC3, which is known in the art. Applicants respectfully request reconsideration and withdrawal of the rejection.

### **Enablement Rejections**

The claims also remain rejected under 35 U.S.C. § 112, first paragraph as being non-enabled. Applicants respectfully traverse. The issue is whether the increased GPC3 in the test sample is useful as a method for detecting hepatic cancer. The answer is “yes.” Therefore the claim is enabled because a person of ordinary skill in the art would be able to measure the GPC3 in the sample, and determine whether that level was “greater than the normal levels” from a corresponding sample type, and thereby be enabled to “detect” hepatic cancer.

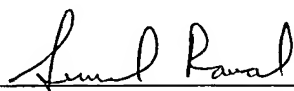
There is no requirement that the skilled artisan use ONLY the claimed method as a final determination before treatment. Therefore, the “practical issue” raised in the Office

Action regarding treating a cirrhotic person using a cancer treatment is completely inapposite. The claimed method, notably, does not include a treatment step. The issue is whether a skilled artisan can practice the invention as claimed. Clearly, as disclosed in the subject application, one of ordinary skill can determine whether a test sample (blood, serum, or plasma) contains "greater levels" of GPC3 than the levels of GPC3 found in a normal control, and thereby detect hepatic cancer. Applicants maintain that such detection would not require undue experimentation. It is respectfully submitted that the subject claims are enabling, and reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph, is respectfully requested.

### **CONCLUSION**

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,  
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